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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,724	07/20/2005	Tohru Kambe	Q89067	5408
23373	7590	05/01/2006	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			CHU, YONG LIANG	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/542,724	KAMBE ET AL.	
	Examiner	Art Unit	
	Yong Chu	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received. JP2003-011936
2. ☒ Certified copies of the priority documents have been received in Application No. JP2003-289954
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/20/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim 10 is cancelled by amendment filed on 20 July 2005. Claims 7-8 are amended by amendment filed on 20 July 2005. Therefore, claims 1-9 are currently pending in the instant application.

Priority

This application is a 371 of PCT/JP04/00419, filed on 20 January 2004. Applicants claim the benefit of for Japan Patent Application 2003-011936 filed on 21 January 2003 and 2003-289954 filed both on 8 August 2003, under 35 U.S.C. §119(a-d).

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

Lack of Unity Requirement

Claims 1-9 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

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PCT Rule 13.2 states unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1 (b), provides that "special technical features" mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part 1 (e), provides combinations of different categories of claims and states:

"The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

- (i) in addition to an independent claim for a given product, an independent claims for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product, or
- (ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specially designed for carrying out the said process, or
- (iii) in addition to an independent claim for a given product, and independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specially designed for carrying out the said process,..."

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I: Claims 1-8 are drawn to a compound or composition which contains at least one compound of formula (I) according to claim 1. If this group is elected, Applicant is requested to elect a single species for search purposes. This group is subject to further restriction, if elected.

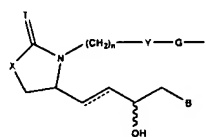
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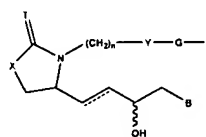
Group II: Claim 9 is drawn to a method for preventing and/or treating EP4-mediated disease, comprising the administration of a mammal an effective amount of a compound of claim 1.

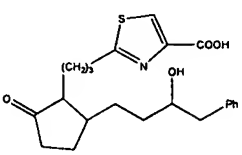
In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The claims herein lack unity of invention under PCT Rules 13.1 and 13.2 because, pursuant to 37 C.F.R. 1.475(a) **Groups I-II** lack unity of invention since under 37 CFR 1.475:

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical feature among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.



The structural moiety common to **Groups I-II** is . This technical feature is not a special technical feature, because it fails to define a contribution over

the compound  of the prior art of Cameron et al. WO2002042268.

Therefore, claims 1-9 are not so linked as to form a single general inventive concept and there is a lack of unity of invention. The variables vary extensively and when taken as a whole result in vastly different compounds. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter impose a serious burden on any examination of the claimed subject matter.

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Because the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to a product, a process for the manufacture of said product, or a method of use.

Furthermore, with respect to **Groups I-II**, even if unity of invention under 37 CFR 1.475(a) is not lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specially designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specially designed for carrying out the said process.

Moreover, according to 37 CFR 1.475(c),

If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

In the instant case the claims are drawn to more than one product, process, and method of use. According to 37 CFR 1.475(e),

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

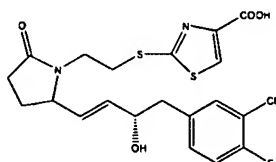
As a result, the claims lack unity of invention and applicant is required to elect a single invention.

The claims directed to a single method of preparation and a single method of use will be examined along with the elected invention so long as it is commensurate in scope therewith.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even if the restriction requirement is traversed (37 CFR 1.143).

Response to Restriction

During a telephone conversation with Applicants' representative, Mark Boland, 18 April 2006, an election was made without traverse to **Group I: Claims 1-8** and the



specific compound of Example 15(11) is acknowledged.

As previously stated in the restriction requirement, in accordance with M.P.E.P. 821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims and method of use claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until such time, a restriction between product claims and process is deemed proper.

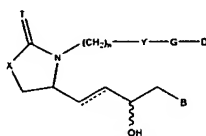
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

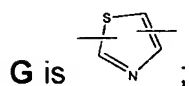
Status of the Claims

The scope of the invention of the elected subject matter is as follows:



Compounds of formula (I), , depicted in claim 1, wherein:

D is COOR¹, wherein **R**¹ is hydrogen or C₁₋₄ alkylene;



Y is a single bond or -S-;

T is O or S;

X is -CH₂-;

Ring **B** is C3-7 cycloalkyl optionally substituted;

Q and **n** are defined in claim 1.

As a result of the election and the corresponding scope of the invention identified supra, the remaining subject matter of claims 1, 3-8 and 9 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The subject matter which are withdrawn from consideration as being non-elected subject differ materially in structure and composition and have been restricted properly a reference which anticipated but the elected subject matter would not even render obvious the withdrawn subject matter and the fields of search are not co-extensive.

Therefore, Claims 1 (in part), and 3-6 (in part), and 7-8 are ready to examine.

Specification

The first paragraph of the specification does not contain continuing data to which the instant specification claims benefit from.

Claim Objections

Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 8 is a duplicate of claim 7.

Claim Rejections - 35 USC § 102(b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

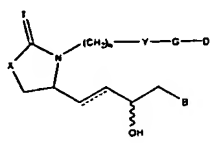
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

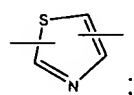
Claim 1 is rejected under 35 U.S.C. 102 (b) as being anticipated by Cameron et al., US 2002/0065308 (now U.S. Patent 6,552,067).

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Applicants instant elected invention in claim 1, 7 and 8 teaches compounds of

formula (I) , depicted in claim 1, and their a pharmaceutically acceptable salts thereof wherein:

D is COOR¹, wherein **R**¹ is hydrogen or C₁₋₄ alkylene;

G is ;

Y is a single bond or -S-;

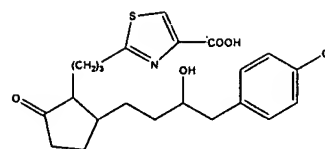
T is O or S;

X is -CH₂-;

Ring **B** is C3-7 cycloalkyl optionally substituted;

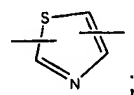
Q and **n** are defined in claim 1.

Cameron et al. teach specific compounds (Example 3B)



of page 33, read on the instant claims 1 wherein:

D is COOR¹, wherein **R**¹ is hydrogen;

G is ;

Y is a single bond;

T is O;

X is -CH₂-;

Ring **B** is phenyl, wherein **R**³ is Cl, and **q** is 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

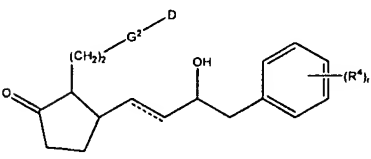
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

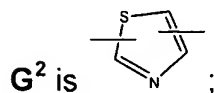
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5-6 are rejected under 35 U.S.C. 103 (a) as unpatentable over Cameron et al., US 2002/0065308 (now U.S. Patent 6,552,067).

Applicants instant elected invention in claims 5-6 teach compounds of formula (I-

2), , depicted in claim 5, and their pharmaceutically acceptable salts thereof wherein:



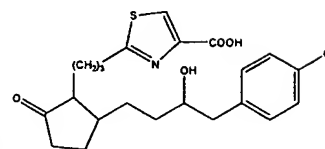
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D is COOR¹, wherein R¹ is hydrogen;

R⁴ is halogen, alkyl,...;

r is 0, or an integer 1-5.

Determination of the scope and content of the prior art (MPEP §2141.01)



Cameron et al. teach a specific compound of formula,

of

Example 3B, depicted on page 33 of the Specification. Cameron et al. teach a group of similar compounds of Example 3A-3M, depicted on page 33-39 of the Specification.

The examples listed are the compounds useful as EP4 receptor selective agonists. The anticipating species was delineated *supra*.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the prior art of Cameron et al. and the instantly claimed compounds, is that -(CH₂)₃- of the compounds of Cameron et al. could be -(CH₂)₂- of the instantly claimed compounds, and they are use for the same application.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

One skilled in the art would have found the claimed compound prima facie obvious because it is well established that the substitution of -(CH₂)₃- for -(CH₂)₂- on a known compound is not a patentable modification absent unexpected or unobvious results. In re Wood, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and In re Lahr, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity as EP4 receptor selective agonists.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

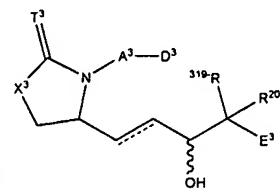
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

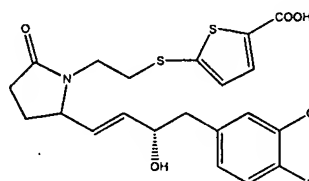
Claims 1, and 3-6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of Maruyama *et al.* U.S. Pat. App. Num. 2003/0020686 in view of Cameron *et al.* U.S. Patent Application Number 2002/0065308 (now U.S. Patent 6,552,067).

Determination of the scope and content of the prior art (MPEP § 2141.01)

Maruyama *et al.* teach a compound of formula (I-3)



in claim

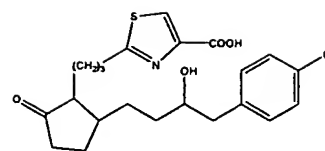


15 as EP4 agonist with a specific compound

as example 25(b) on

page 270 of the prior art.

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Cameron et al. teach a specific compound of formula, of

Example 3B, depicted on page 33 of the Specification. Cameron et al. teach a group of similar compounds of Example 3A-3M, depicted on page 33-39 of the Specification.

The examples listed are the compounds useful as EP4 receptor selective agonists.

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The difference between the prior art of Maruyama et al. and the instant claims is that the prior art does not teach the exact equation in claim 1. Cameron et al. teach a specific on page 33-39 of the Specification leading to the same claims.

Finding of prima facie obviousness - rationale and motivation (MPEP § 2142-2413)

One skilled in the art would have found the claimed compound prima facie obvious because it is well established that the substitution of -(CH₂)₃- for -(CH₂)₂- on a known compound is not a patentable modification absent unexpected or unobvious results. In re Wood, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and In re Lahr, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity as EP4 receptor selective agonists.

This is a provisional obvious double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

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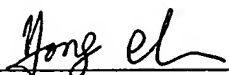
Telephone Inquiry

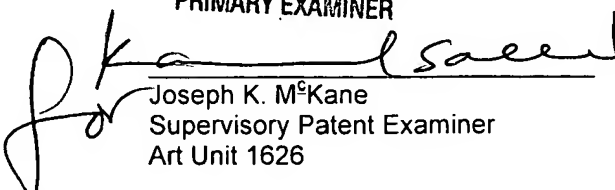
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759.

The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. M^cKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Yong Chu, Ph.D.
Patent Examiner
Art Unit 1626

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

Joseph K. M^cKane
Supervisory Patent Examiner
Art Unit 1626